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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/812,034	03/19/2001	Stephen L. Mayo	A-65353-6/RFT/RMS/RMK	3845

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EXAMINER

KIM, YOUNG J

ART UNIT

PAPER NUMBER

1637

DATE MAILED: 02/11/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/812,034

Applicant(s)

MAYO ET AL.

Examiner

Young J. Kim

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 November 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 30-50 and 53-60 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 30-50 and 53-60 is/are rejected.
- 7) ☒ Claim(s) 45 and 46 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

This Office Action responds the Amendment received on November 25, 2002 (Paper No. 6).

Objections & Rejections Withdrawn

Claim Objections

The objection of claims 4-22 for being dependent on a canceled claim, in the Office Action mailed on August 27, 2002 is withdrawn in view of the Amendment received on November 25, 2002, canceling the claims.

Claim Rejections - 35 USC § 112

The rejection of claims 2-29, 31-50, and 52 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter, in the Office Action mailed on August 27, 2002 is withdrawn in view of the Amendment received on November 25, 2002.

Claim Rejections - 35 USC § 102

The rejection of claims 22-28 under 35 U.S.C. 102(b) as being anticipated by Hardman (U.S. Patent No. 4,939,666, issued July 3, 1990), in the Office Action mailed on August 27, 2002 is withdrawn in view of the Amendment received on November 25, 2002, canceling the claims.

Claim Rejections - 35 USC § 103

The rejection of claims 24 and 29 under 35 U.S.C. 103(a) as being unpatentable over Hardman (U.S. Patent No. 4,939,666, issued July 3, 1990) in view of Lee et al. (U.S. Patent No. 5,241,470, issued August 31, 1993), in the Office Action mailed on August 27, 2002 is withdrawn in view of the Amendment received on November 25, 2002, canceling the claims.

Double Patenting

The objection of claim 18 for being a substantial duplicate of claim 31, in the Office Action mailed on August 27, 2002 is withdrawn in view of the Amendment received on November 25, 2002, canceling the claim.

The provisional rejection of claims 2-10, 12-17, 19-29 under 35 U.S.C. 101 as claiming the same invention as that of claims 1-27 of copending Application No. 09/837,886, in the Office Action mailed on August 27, 2002 is withdrawn in view of the Amendment received on November 25, 2002, canceling the claims.

The rejection of claims 2-10 and 12-17 under 35 U.S.C. 101 as claiming the same invention as that of claims 2-15 of prior U.S. Patent No. 6,188,965, in the Office Action mailed on August 27, 2002 is withdrawn in view of the Amendment received on November 25, 2002, canceling the claims.

The rejection of claims 30-52 under 35 U.S.C. 101 as claiming the same invention as that of claims 2-15 of prior U.S. Patent No. 6,269,312, in the Office Action mailed on August 27, 2002 is withdrawn in view of the arguments presented in the Amendment received on November 25, 2002.

The rejection of claim 2 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 2 of U.S. Patent No. 6,188,965, in the Office Action mailed on August 27, 2002 is withdrawn in view of the Amendment received on November 25, 2002, canceling the claim.

The rejection of claims 2, 6, 11, and 19-22 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 2, 6, 11, and 18-21 of U.S.

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Patent No. 6,269,312, in the Office Action mailed on August 27, 2002 is withdrawn in view of the Amendment received on November 25, 2002, canceling the claims.

Objections & Rejections – New Grounds

Claim Objections

Claims 45 and 46 are objected to for the below reason.

A series of singular dependent claims is permissible in which a dependent claim refers to a preceding claim which, in turn, refers to another preceding claim.

A claim which depends from a dependent claim should not be separated by any claim which does not also depend from said dependent claim. It should be kept in mind that a dependent claim may refer to any preceding independent claim. In general, applicant's sequence will not be changed. See MPEP § 608.01(n).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 47-50 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

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Claims 47-50 are product-by-process claims drawn to an optimized protein made by the method claims, a nucleic acid sequence encoding the optimized protein, an expression vector comprising the nucleic acid, and a host cell comprising the nucleic acid.

MPEP states that:

“A biomolecule sequence described only by a functional characteristic, without any known or disclosed correlation that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence” (MPEP 2163(a)).

The specification discloses a few protein sequences (Gβ1, FSD-1) and their optimization. However, the claims are drawn to any and every protein derived from the claimed process. The claims fails to disclose a correlation between the function and structure of every protein, the nucleic acid encoding the protein, a vector comprising the nucleic acids, etc. Furthermore, there is no basis on which to search for what is being claimed. Because Applicants have not disclosed a sufficient number of species within the genus to which the claims are drawn, the claims lack in their written description as required under 35 U.S.C. 112, first paragraph.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 40, 57, and 58 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claim 40 is indefinite for reciting the term, "said atomic solvation scoring function," which lacks proper antecedent basis. It appears that claim 40 should depend on claim 36 for proper antecedent basis.

Claims 57 and 58 are indefinite for reciting the term, "said first and second sets of rotamers," which lacks proper antecedent basis. The base claim 56 appears to indicate that for each residue position (which is variable), there exists rotamers of at least two different amino acid side chains. The base claim, however, lacks the concept of first and second sets of rotamers.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 30-52 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-23 of U.S. Patent No. 6,269,312 B1.

Although the conflicting claims are not identical, they are not patentably distinct from each other for the below reasons.

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Preliminarily, the amendment made to the above claims is directed to establish proper antecedent basis as well as rewording of some of the claims, thus not substantive in the scope of the invention.

As Applicants point out in their response received on November 25, 2002, the difference between the claims of the instant application versus the claims of the '312 patent is the term "amino acids," used in the instant application versus the term, "rotamers" in the '312 patent. Applicants site a section of the specification (also present in the '312 patent) wherein the specification states that "each amino acid can be represented by a discrete set of all allowed conformers of each side chain, called rotamers" (column 5, lines 54-55). In other words the amino acids are represented by "rotamers." The specification of the '312 patent adds that, "[t]hus, to arrive at an optimal sequence for a backbone, all possible sequences of rotamers must be screened, where each backbone position can be occupied by either each amino acid in all its possible rotameric states, or a subset of amino acids, and **thus a subset of rotamers** (column 5, 55-60). The specification discloses no others "species" which would represent the "genus" of attributes of amino acids, other than the species of rotamers.

The current situation is analogous to that which was described in *In re Vogel* (164 USPQ 619, CCPA, 1970), wherein the court stated that:

"The correctness of this conclusion is demonstrated by observing that claim 10, by reciting 'meat' includes 'pork.' Its allowance for a full term would therefore extend the time of monopoly as to the pork process" (623).

In a similar manner, an allowance of the present claims drawn to a method using the amino acids would include the method using the rotamers of the '312 patent, thereby extending the time of monopoly to the method using the rotamers.

Because the specification of the '312 patent contemplates only one species within the genus of attributes of amino acids, the claims of the instant application is clearly indistinct over the claims of the '312 patent.

Claims 53-55 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 2 of U.S. Patent No. 6,269,312 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other for the following reasons.

Preliminarily, the claims of the instant application uses the term "amino acids" while the '312 patent uses the term, "rotamers," the obvious relationship of the terms explained above.

Claims 53-55 of the instant application and claim 2 of the '312 patent are both drawn to a method of optimizing a protein sequence. The only notable difference between the two claims is that claim 53 (the base claim) of the instant patent recites the phrase, "and wherein a second group for a second variable position has a second set of at least two different amino acid side chains, which claim 2 of the '312 patent leaves out. However, claim 2 of the '312 patent recites, "establishing a group of potential rotamers for each of said variable residue positions, wherein **the group of potential rotamers for at least one of said variable residue position has a rotamer selected from each of at least two different amino acid side chains.**" The claim is open to additional groups, such as "second group" of the present claim. In addition, claim 2 of

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the '312 patent clearly recites the nature of the first group, wherein the group has a rotamer selected from each of at least two different amino acid side chains," which is the same for the second group of the instant claim. Therefore, one of ordinary skill in the art would recognize that the spirit of claim 2 clearly encompasses the instant claim 53, though slightly different in wording.

Claims 56-60 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 2, 7, and 12 of U.S. Patent No. 6,269,312 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other for the below reasons.

Preliminarily, the claims of the instant application as well as the '312 patent use the term, "rotamers."

Claim 2 of the '312 patent and claim 56 of the instant application is identical in their step except sub-step (c) of claim 56 which adds the phrase (in bold), "establishing a group of potential rotamers for each of said variable residue positions, wherein the group for at least one variable residue position has rotamers of at least two different amino acid chains, **and wherein at least one of said amino acid side chains is from a hydrophilic amino acid.**" However, claim 7 of the '312 patent provides for a scoring function which include an atomic solvation function which accounts for hydrophilic amino acids. In addition, the limitation of claim 56 is a quality of what is being processed which does not alter the method itself. The method claim of claim 7 of '312 patent would fully be able to optimize a protein sequence wherein at least one of the amino acids in consideration is from a hydrophilic amino acid. With regard to the limitation of claim 59, drawn to different kinds of hydrophilic amino acids, one of ordinary skill in the art is

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well aware of what amino acids are hydrophilic. With regard to the limitation of claim 60 which comprise physically generating the optimized protein sequences and experimentally testing the sequence for desired function, claim 12 (directly dependent on claim 2) recites such limitation.

Therefore, the invention as claimed is patentably indistinct from the '312 patent.

Conclusion

No claims are allowed.

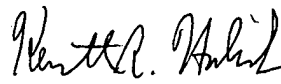
Inquiries

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Young J. Kim whose telephone number is (703) 308-9348. The Examiner can normally be reached from 8:30 a.m. to 7:00 p.m. Monday through Thursday. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Gary Benzion, can be reached at (703) 308-1119. Papers related to this application may be submitted to Art Unit 1637 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If applicant does submit a paper by FAX, the original copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office. The Fax number is (703) 746-3172. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Young J. Kim

2/5/03




KENNETH R. HORLICK, PH.D
PRIMARY EXAMINER

2/6/03